Initial Approval: April 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Topiramate Extended Release

PROVIDER GROUP: Pharmacy

MANUAL GUIDELINES: All dosage forms of the medications listed below will require prior authorization.
Qudexy XR® (topiramate extended-release)
Trokendi XR® (topiramate extended-release)

For all agents listed above, the preferred PDL drug, if applicable, which covers that specific indication, is required unless the patient has a documented clinical rationale for using the non-preferred agent, which is supported by the label.

CRITERIA FOR INITIAL APPROVAL FOR ALL PRODUCTS (DRUG-SPECIFIC CRITERIA DEFINED IN TABLE 1): (must meet all of the following)

- Medication must be prescribed for an FDA-approved indication.
- For use in migraine prophylaxis, the patient must meet the following step-therapy criteria:
    - Patient must have experienced an inadequate response after a trial of at least one agent from each medication class listed in Table 2 at a maximum tolerated dose, OR have a documented intolerance or contraindication to all preventive therapies.
    - Patient must have experienced an inadequate response to a trial of onabotulinumtoxinA (Botox®) (trial of at least 60 days) for chronic migraine treatment, OR have a documented intolerance or contraindication to treatment with onabotulinumtoxinA (Botox®).
    - Patient must have experienced an inadequate response to a trial of a CGRP antagonist agent listed in Table 3 (trial of at least 60 days) for chronic migraine treatment OR have a documented intolerance or contraindication to treatment to all CGRP targeted therapies.
    - The patient has experienced a reduction in the number of monthly headache days compared to baseline while using topiramate immediate-release formulation.
    - Prescriber must provide documentation of all previous medication trials. Documentation must include the medication name(s), trial date(s) and outcome(s) of the trial (i.e. inadequate response, intolerance or contraindication).
- Medication must be prescribed within an FDA-approved age range, as defined in Table 1.
- Medication must be prescribed by or in consultation with a neurologist
- Dose of medication requested must be consistent with FDA-approved labeling, as defined in Table 1.

LENGTH OF APPROVAL: 6 months

RENEWAL CRITERIA:

- The patient has experienced a significant reduction in the number of monthly headache days compared to previous treatment with the topiramate-immediate release formulation.
- The patient has experienced a reduction in the number of monthly headache days of at least moderate severity compared to baseline.

LENGTH OF APPROVAL: 12 months

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE

TABLE 1. MEDICATION-SPECIFIC CRITERIA

INDICATION	MEDICATION	AGE (years)	DOSING LIMIT
Lennox-Gastaut Syndrome (LGS)	Qudexy XR	≥ 2	400 mg daily
	Trokendi XR	≥ 6	400 mg daily
Migraine Prophylaxis	Qudexy XR	≥ 12	100 mg daily
	Trokendi XR	≥ 12	100 mg daily
Partial Onset Seizures	Qudexy XR	≥ 2	400 mg daily
	Trokendi XR	≥ 6	400 mg daily
Primary Generalized Tonic-Clonic Seizures	Qudexy XR	≥ 2	400 mg daily
	Trokendi XR	≥ 6	400 mg daily

TABLE 2. PRIOR PREVENTATIVE MIGRAINE THERAPIES

BETA-BLOCKING AGENTS	ANTIEPILEPTIC AGENTS
Propranolol	Topiramate
Metoprolol	Valproic acid
Timolol	Divalproex

TABLE 3. CGRP-TARGETED MIGRAINE PROPHYLAXIS THERAPIES

CGRP-TARGETED THERAPIES
Erenumab-aooe (Aimovig™)
Fremanezumab-vfrm (Ajovy™)
Galcanezumab-gnlm (Emgality™)